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COVID-19 vaccines are NOT fully approved by the TGA

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To: Brendan.Murphy@health.gov.au

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For the attention of:

Professor Brendan Murphy

Secretary of the Australian Department of Health

Chair of the COVID-19 Vaccines and Treatments for Australia - Science and Industry Technical Advisory Group

Professor Murphy

You recently assured Australians that the Pfizer and AstraZeneca vaccine products have **"gone through the normal, full range of regulatory approvals for our vaccines...we have been able to do the full, safe, regulatory approval...we have not cut any corners"** and **"...we decided that to get the confidence of the people in Australia, because we had no community transmission, we were not going to do anything other than our full normal registration process"**, during an interview with Leigh Sales on the ABC's 7.30 program on 3 February 2021. (See copy of transcript attached.)

Your statements were in response to Leigh Sales' questions *"...what is your message to any Australian who might be legitimately worried thinking, 'This has happened all pretty quickly. I'm sort of worried. Is it going to be safe to have a vaccine? What is your official advice on that?'"* (My emphasis.)

Professor Murphy, I suggest your 'official advice' on this matter is misleading because **in fact both the Pfizer and AstraZeneca vaccine products have only been given 'provisional' approval by the TGA. This has not been made clear to the Australian public.**

The TGA provisional approval statement for both the Pfizer COMIRNATY[1] and COVID-19 Vaccine AstraZeneca[2] vaccine products states: (See copies attached.)

"Provisional approval of this vaccine is valid for two years and means it can now be legally supplied in Australia. The approval is subject to certain strict conditions, such as the requirement for (Pfizer/AstraZeneca) to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post market assessment. (Pfizer COMIRNATY/COVID-19 Vaccine AstraZeneca) has been shown to prevent COVID-19 however it is not yet known whether it prevents transmission or asymptomatic disease." (My emphasis.)

Professor Murphy, I again suggest you have misled Australians about the TGA approval for the Pfizer and AstraZeneca vaccine products.

These vaccine products have **not** been fully approved, and it is **not** yet known whether they prevent transmission or asymptomatic disease.

The Pfizer and AstraZeneca vaccine products are **provisionally approved** for two years, and the TGA will be relying on manufacturer supplied data to judge the longer term efficacy and safety from ongoing clinical trials and **post-market assessment**. 'Post-market assessment' indicates people being vaccinated in the community are now part of the clinical trials assessing these vaccine products - **are people being informed they are part of a vaccine clinical trial? Are these people giving their consent to being involved in a vaccine clinical trial with these provisionally approved vaccine products?**

It's on the record I have brought this matter to your attention Professor Murphy, as witnessed by other members of the COVID-19 Vaccines and Treatments for Australia - Science and Industry Technical Advisory Group copied on this email.

This email will be forwarded to Prime Minister Scott Morrison, Health Minister Greg Hunt and other parties.

Sincerely

Elizabeth Hart

Independent person investigating the over-use of vaccine products and conflicts of interest in vaccination policy

References:

1. TGA provisionally approves Pfizer COVID-19 vaccine. 25 January 2021.
2. TGA provisionally approves AstraZeneca's COVID-19 vaccine. 16 February 2021.

3 attachments

Dr Brendan Murphy answers questions about the safety of the COVID vaccine - 7.30.pdf

119K



TGA provisionally approves AstraZeneca's COVID-19 vaccine (TGA).pdf

102K



TGA provisionally approves Pfizer COVID-19 vaccine (TGA).pdf

94K